STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
FACILITY LICENSING AND INVESTIGATIONS SECTION

IN RE: Bristol Hospital, Inc. of Bristol, CT d/b/a
Bristol Hospital
Brewster Road
Bristol, CT 06010

CONSENT ORDER

WHEREAS, Bristol Hospital, Inc. (hereinafter the "Licensee"), has been issued License No.0041 to operate a General Hospital known as Bristol Hospital, (hereinafter the "Facility") under Connecticut General Statutes Section 19a-490 by the Department of Public Health, State of Connecticut (hereinafter the "Department"); and

WHEREAS, the Facility Licensing and Investigations Section (hereinafter the "FLIS") of the Department conducted unannounced inspections on various dates commencing on April 23, 2008 and concluding on October 7, 2008; and

WHEREAS, the Department, during the course of the aforementioned inspections identified violations of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies in a violation letter dated October 29, 2008 (Exhibit A – copy attached); and

WHEREAS, the Licensee, without admitting wrongdoing, is willing to enter into this Consent Order and agree to the conditions set forth herein.

NOW THEREFORE, the FLIS of the Department acting herein and through Joan Leavitt its Section Chief, and the Licensee, acting herein and through Kurt Barwis, its President/CEO, hereby stipulate and agree as follows:

1. The Licensee shall, within fourteen (14) days of the execution of this Consent Order, review and revise, as applicable, policies and procedures relative to:

a. Physician orders for intravenous medication administration, which at a minimum shall include the medication, specific dosage ranges, dosage increments, frequency and reason for medication;
b. Parameters for intravenous pain control and intravenous drip medication administration;
c. Procedure to address staff person responsible for medication preparation, inclusive of volume and solution;
d. Patient assessments to determine intravenous analgesic effect and possible negative outcomes relative to medication administration;
e. Supervision of clinical staff regarding adherence to policies and procedures for intravenous analgesic medications relative to prescribing medications, medication administration, patient assessment and remediation of staff who fail to adhere to the relevant policies and procedures; and
f. Pharmacy, including orders, preparation, labeling and dispensing of medication.

2. Within forty-five (45) days of the completion of the revision of facility policies and procedures required by this Consent Order, the Medical Board shall review and approve revisions to said policies and procedures.
3. A pharmacist shall review, on a weekly basis, one hundred percent (100%) of all IV medication regarding titration for compliance with standards of practice and Facility policy and procedure. Such review shall continue for ninety (90) days following the execution of the Consent Order.
4. The pharmacist shall document said audits and issues identified. Documentation of the audits shall be maintained for a period of two (2) years.
5. The Licensee shall develop and provide educational courses in a Grand Rounds format to applicable Facility professional staff which shall include, but not be limited to:
    a. Patient assessments including physical components;
    b. Pharmacology regimes and their potential interactions with other medications and/or medical/physical conditions; and
    c. Current standards of practice/trends specific to medication titration protocols.

6. Within twenty-one (21) days of the execution of this Consent Order, the Director of Nurses shall develop and/or review and revise, as necessary, policies and procedures related to:
    a. Patient rights, including but not limited to the patient's right to participate in the development of the plan of care, the right to make informed decisions regarding care, and the right to formulate advanced directives; and
    b. Prevention, assessment and monitoring of patients at risk for and with actual pressure ulcers and the delivery of direct patient care with particular emphasis and focus on the delivery of nursing services by registered nurses, licensed practical nurses, nurse aides.
7. Within forty (40) days of the effect of the Consent Order all medical and nursing staff shall be inserviced, as applicable, to the policies and procedures identified in paragraph numbers one (1) and (6) and shall implement prompt training and/or remediation in areas in which a staff member demonstrated a deficit regarding implementation of Facility policies/procedures.
8. Effective upon the execution of this Consent Order, the Licensee, through its Governing Body, Administrator and Director of Nursing Services, shall ensure substantial compliance with the following:
    a. Sufficient nursing personnel are available to meet the needs of the patients;
    b. Patient treatments, therapies and medications are administered as prescribed by the physician and in accordance with each patient's comprehensive care plan;
    c. Patient assessments are performed in a timely manner and accurately reflect the condition of the patient; and
    d. Each patient care plan is reviewed and revised to reflect the individual patient's problems, needs and goals, based upon the patient assessment and in accordance with applicable federal and state laws and regulations.
9. Within thirty (30) days of the execution of this Consent Order, the Licensee shall review, revise and/or develop policies and procedures related to MRI safety precautions and practices regarding the care of the patient undergoing an MRI.

10. Within forty-five (45) days of the execution of this Consent Order, the Licensee shall review or implement and revise, as applicable:
    a. Measures to ensure that fluoroscopy/MRI equipment is operated by individuals who have received education and have demonstrated competency regarding the operation of the particular equipment; and
    b. A preventative maintenance program is implemented and maintained for clinical equipment and any repairs made to said equipment. Documentation shall be maintained for preventative maintenance and/or work orders for three (3) years and shall be made available to the Department upon request.
11. The Licensee, within seven (7) days of the execution of this document, shall designate an individual within the Facility to monitor the requirements of this Consent Order. The name of the designated individual shall be provided to the Department within said timeframe.
12. The Licensee shall, as part of its Quality Assurance/Performance Improvement Program, analyze data and track pertinent indicators relative to the protection of patient rights including informed consent and the formulation and implementation of advanced directives. Also, the Quality Assurance Program in conjunction with the Pharmacist shall track staff performance and analyze data regarding the ordering and/or administering of intravenous analgesic drip medication in accordance with current standards of care. The Licensee shall incorporate into its Quality Assurance Program indicators to track and analyze data pertinent to the prevention and care of patients at risk for and/or with actual skin impairment.
13. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Agreement shall be made available to the Department upon request.
14. The Vice President of Nursing Services shall meet in person or by teleconference with the Department every six (6) weeks for the first three (3) months this Consent Agreement is in effect and thereafter as requested by the Department. The meetings shall include discussions of issues related to the care and services provided by the Licensee and the Licensee's compliance with applicable Federal and State laws and regulations.

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15. The Licensee shall pay a monetary penalty to the Department in the amount of ~~five~~ four thousand dollars ($4,000.00), by money order or bank check payable to the Treasurer of the State of Connecticut and mailed to the Department within (2) weeks of the effective date of this Consent Order. The money penalty and any reports required by this document shall be directed to:

Elizabeth Andstrom, MS, RN, Supervising Nurse Consultant
Facility Licensing and Investigations Section, Department of Public Health
410 Capitol Avenue, P.O. Box 340308 MS #12HSR
Hartford, CT 06134-0308

16. All parties agree that this Consent Order is an Order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of the Consent Order or of any other statutory or regulatory requirements or any other administrative and judicial relief provided by law. This Consent Order may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. The Licensee retains all of its rights under applicable law.
17. The terms of this Consent Order shall remain in effect for a period of two (2) years from the effective date of this document unless otherwise specified in this document.
18. The Licensee understands that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive the Licensee of any other rights that it may have under the laws of the State of Connecticut or of the United States.
19. Should the Licensee not be able to maintain substantial compliance with the requirements of the Consent Order the Department retains the right to issue charges to encompass the findings identified in the October 29, 2008 violation letter referenced in this document.
20. The Licensee had the opportunity to consult with an attorney prior to the execution of this Consent Order.

WITNESS WHEREOF, the parties hereto have caused this Consent Order to be executed by their respective officers and officials, which Consent Order is to be effective as of the later of the two dates noted below.

Bristol Hospital, ~~Inc~~ of Bristol – Licensee

12-30-08
Date

By: _____
Kurt Barwis, President/CEO

STATE OF Connecticut)

County of Hartford) ss 12-30- 2008

Personally appeared the above named _____ and made oath to the truth of the statements contained herein.

JILL RUSGROVE
NOTARY PUBLIC
MY COMMISSION EXPIRES OCT. 31, 2008

My Commission Expires: _____
(If Notary Public)

Jill M Rusgrove

Notary Public	[✓]
Justice of the Peace	[ ]
Town Clerk	[ ]
Commissioner of the Superior Court	[ ]

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

12/30/08
Date

By: Wendy H. Furniss
~~Joan D. Leavitt, R.N., M.S., Section Chief~~
~~Facility Licensing and Investigations Section~~
Wendy H. Furniss, RN, M.S.
Branch Chief
Health Care Systems Branch

STATE OF CONNECTICUT

EXHIBIT A

DEPARTMENT OF PUBLIC HEALTH

October 29, 2008

Kurt Barwis, President/CEO
Bristol Hospital
Brewster Road
Bristol, CT 06010

Dear Mr. Barwis:

Unannounced visits were made to Bristol Hospital commencing on April 23, 2008 and concluding on October 7, 2008, by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a licensure renewal inspection, a substantial allegation survey and full survey at the request of CMS and to conduct multiple investigations.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for November 13, 2008 at 10:00 AM in Room 2F in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish legal representation, please feel free to have an attorney accompany you to this meeting.

Please submit a plan of correction for the identified violations to be presented at this meeting which includes the following components:

- Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
- Date corrective measure will be effected.
- Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Ann Marie Montemerlo, R.N.,
Supervising Nurse Consultant
Facility Licensing and Investigations Section

AMM:zbj

c. Director of Nurses
Medical Director
CT#7919, #7526, #7679, #7523

Phone: (860) 509-7400
Telephone Device for the Deaf (860) 509-7191
410 Capitol Avenue - MS # 12HSR
P.O. Box 340308 Hartford, CT 06134
An Equal Opportunity Employer

EXHIBIT A

DATES OF VISITS: Commencing on April 23, 2008 and concluding on October 7, 2008

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (4)(A) and/or (d) Medical records (3) and/or (8) and/or (e) Nursing services (1) and/or (i) General (6).

1. *Based on clinical record reviews and interviews with facility personnel, the facility failed to ensure informed consent regarding resuscitative status was obtained according to hospital policy for Patients #1 and 9. The findings include:

   a. Patient #1 was admitted to the hospital on 10/5/07 at 10:35 AM with shortness of breath. Patient #1 was diagnosed with congestive heart failure and acute MI. Review of the advance directives dated 10/5/07 (completed when admitted to the intensive care unit 3:00-4:00 PM) identified that the patient wanted cardiopulmonary resuscitation and ventilation with no tracheostomy and no feeding tube. Patient #1 was determined to be alert and oriented at that time. As Patient #1's medical condition deteriorated. MD #4 and the health care agent changed the code status to "comfort measures only." Further review of the medical record failed to identify that the patient was consulted or was incapacitated in regard to the decision to change the resuscitative orders. The patient's Bipap was discontinued, a morphine drip was initiated at approximately 7:30 PM and the patient expired at 10:15 PM.

   b. Patient #9, a 76 year old female, was admitted to the hospital on 5/24/08 with diagnoses that included metastatic ovarian cancer. Review of the Admission Assessment on 6/2/08 indicated that the patient was awake, confused and did not have an advance directive. Review of the admission Physician's Order Sheet dated 5/24/08 identified that the patient was a Category A, however, the telephone order was not signed by the physician. Review of the Policies for Resuscitative Status Orders identified that a Category A was full support, a Category B would receive any/all treatments to prevent an arrest except for resuscitation and a Category C was do not resuscitate and no additional treatments. The physician must order the Category A, B or C. Furthermore, if the Resuscitative Status order is a telephone order, the physician must sign it within 24 hours. Review of the Multidisciplinary Plan of Care dated 5/24/08 reflected a resuscitation discrepancy and noted that the patient was a DNR status "A", however, the patient goal of the day indicated that the patient was "CMO" (comfort measures only) with no date noted. Although the Physician Progress Note dated 5/31/08 identified family communication regarding poor patient prognosis and CMO discussion, the Resuscitative Status Order Sheet failed to reflect informed consent identification/signature by the family as well as a physician signature and date. Documentation failed to clearly reflect the patient's resuscitative status and/or that informed consent was obtained as per hospital policy.

2. * Based on clinical record reviews and interviews with facility personnel for 4 of 4 sampled patients (Patients #1, #7, #10 and #13), the facility failed to implement advance directives as per hospital policy. The findings include:

DATES OF VISITS: Commencing on April 23, 2008 and concluding on October 7, 2008

EXHIBIT A

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

a. Patient #1 was admitted to the hospital on 10/5/07 at 10:35am with shortness of breath. Patient #1 was diagnosed with congestive heart failure and acute MI. Review of the advance directives dated 10/5/07 (completed when admitted to the intensive care unit-3:00-4:00pm) identified that the patient wanted cardiopulmonary resusitation and ventilation with no tracheostomy and no feeding tube. Patient #1 was determined to be alert and oriented at that time. As Patient #1's medical condition deteriorated, MD #4 and the health care agent changed the code status to "comfort measures only." Further review of the medical record failed to identify that the patient was consulted or was incapacitated in regard to the decision to change the resuscitative orders. Review of the nursing flowsheets dated 10/5/07 identified that the patient received Morphine Sulfate IV push 2mg, and was then started on a Morphine Sulfate IV drip until the patient expired at 10:15 PM. Interview with Person #1 and #2 identified that Patient #1 was alert and orientated until the morphine IV drip was started. Interview with MD #4 identified that she could not recall if she consulted with Patient #1, however she did speak with Patient #1's health care agent about changing the code status due to the patient's poor prognosis. Review of hospital policy identified that informed consent must be obtained from the patient when identifying resuscitative status. If the patient has an advanced directive, the resuscitative order must reflect the patient's wishes as outlined in that directive.

b. Patient #7 had a past medical history of atrial fibrillation and hypertension, and was found unresponsive at home. The patient was brought to the Emergency Department where a CT scan of the head was done and showed bilateral CVA's. The Emergency Room Assessment dated 5/31/08, identified the patient was deemed DNR status and the daughter requested comfort measures only. The BH 398 (consent) form dated 5/31/08, identified the patient had an advanced directive however the current clinical record failed to provide evidence of that advanced directive. On 5/31/08 the resident was admitted to the intermediate care floor and placed on comfort measures only. Interview and review of the clinical record on 6/3/08 at 11:50 AM with the Registered Nurse Manager noted she was initially unable to identify the advanced directive for Patient #7 and after searching, located a living will dated 9/11/07 from a previous admission in an old record. Review of hospital policy identified that if a copy of the advanced directive is provided to the hospital, such document needs to be included in the medical record and/or if the patient has an advanced directive but has not brought the document to the hospital it will be noted on the BH 398 form.

c. Patient #10, an 87 year old female, was admitted to the intensive care unit (ICU) on 5/29/08 with pneumonia and atrial fibrillation. Review of the Policies for Resuscitative Status Orders-Adult Patients identified that all non-pregnant adult patients 60 years of age or older admitted to ICU would have resuscitation orders on admission or within 4 hours. Review of the clinical record failed to identify a code

status. Review of the Admission Assessment dated 5/29/08 reflected that the Advance Directive section was not completed. Review of the Advance Directives for Health Care Policy identified that upon admission, the admitting nurse determines the status and coordinates any necessary follow-up. Although the nursing comment section indicated that information was given, documentation failed to reflect a code status as per policy, as well as Advance Directive follow-up according to the Advance Directive Policy.

d. Patient #13 was admitted to the ICU on 5/30/08 with diagnoses that included respiratory failure and pneumonia. Review of the Admission Assessment dated 5/30/08 reflected that the Advance Directive section was not completed. Review of the Advance Directives for Health Care Policy identified that upon admission, the admitting nurse determines the status and coordinates any necessary follow-up. After surveyor inquiry on 6/3/08, the Advance Directive section identified no Advance Directive per daughter on 6/3/08.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (1)(A) and/or (2) and/or (c) Medical staff (2)(B) and/or (4)(A) and/or (d) Medical records (3) and/or (e) Nursing services (1) and/or (g) Pharmacy (1) and/or (i) General (6).

3. * Based on clinical record reviews and interviews with facility personnel for 7 of 8 sampled patients (Patients #1, #2, #3, #4, #5, #9 and #13), the facility failed to ensure that physician orders were complete and/or were obtained prior to initiating treatment. The findings include:

a. Patient #1 was admitted to the hospital on 10/5/07 with shortness of breath. Patient #1 was diagnosed with congestive heart failure and acute MI. Patient #1's code status was changed to comfort measures only, secondary to poor prognosis. Review of the physician orders dated 10/5/07 identified that the patient was to receive a "morphine sulfate IV drip/titrate to comfort."and "Ativan IV 1mg every two hours as needed". Review of the nursing flowsheets and hospital documentation dated 10/5/07 identified that the patient received Morphine Sulfate IV push 2mg, and was started on a Morphine Sulfate IV drip at 2mg/hr at 7:30 PM. Patient #1's Richmond Sedation Agitation Scale was +1(restless). At 7:45 PM, the Morphine IV drip was increased to 6mg/hr with a sedation score of +1(restless). At 7:49 PM, 7:53 PM, and 7:54 PM, Ativan 1mg IV was given (per pyxis). At 8:00 PM, Patient #1's Morphine IV drip was increased to 15mg/hr, with a sedation score of -2 (light sedation). Patient #1 remained on the Morphine IV drip at 15mg/hr with a sedation score of -3 and then a -5 (unarousable) until she expired at 10:15pm. (55ml in 2 hours). Review of the sedation protocol/order sheet failed to identify specific parameters for dosing and/or level of sedation that was required. Interview with MD #4 identified that she had given a verbal order and would have expected the nurse to start the morphine at 2mg an hour and increase by 1-2mg per hour. The hospital did not have sedation

EXHIBIT A

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

protocols and /or policies that addressed monitoring of patients for sedation. Review of Patient #1's clinical record of 10/5/07 failed to reflect that physician orders and/or progress notes were timed. Interview with the Vice President/Legal Counsel on 4/29/08 identified that all physician orders and progress notes are to be dated and timed.

b. Patient #2 was admitted to the hospital on 4/19/08 with sepsis. Review of the physician's orders dated 4/20/08 identified that the patient was to receive "Propofol IV initiate at 5mcg/kg/min titrate by 5mcg/kg/min every 5 minutes to a max of 50." Further review failed to identify a specific goal for sedation.

c. Patient #3 was admitted to the hospital on 4/15/08 with dehydration and acute renal failure. Review of physician orders dated 4/16/08 identified that the patient was to receive Propofol IV drip at 10mcg, then titrate for sedation. Further review failed to identify specific parameters/protocols for dosing and/or a goal for sedation. Interview with the Nurse Manager on 4/23/08 identified that although the physician is responsible for ordering the sedation score goal, the sedation score usually is determined by the nursing staff.

d. Patient #4 was admitted to the hospital on 4/15/08 with pneumonia. Review of Physician orders dated 4/19/08 identified that the patient was to receive "Propofol IV drip initiated at 5mcg/kg/min to max of 50mcg-titrate per propofol protocol and Levophed for blood pressure if necessary". Further review failed to identify specific parameters/protocols for dosing and/or monitoring. Review of the nursing flowsheets dated 4/19-4/22/08 identified that the patients Propofol IV drip was started at 20mcg.

e. Patient #5 was admitted to the hospital on 4/14/08 with pancreatitis. Review of the physician's orders dated 4/22/08 identified that the patient was to receive Morphine Sulfate IV started at 2mg/hr-titrate to relieve pain/restlessness. Further review failed to identify specific parameters/protocols for dosing and/or monitoring.

f. Patient #9 was admitted to the hospital on 5/24/08 with diagnoses that included metastatic ovarian cancer. Review of the clinical record identified that the patient received an intravenous (IV) morphine infusion during hospitalization. Review of the physician order dated 5/31/08 at 12:30 PM directed Morphine Sulfate drip 1:1 concentration, 1mg per hour, titrate 1 mg per hour for pain and restlessness, maximum dose 5 mg per hour. A second morphine physician order on 5/31/08 (no time) directed that the morphine drip may be increased every (q) 20 minutes for comfort, maximum of 20 mg per hour. Review of the Safe Medication Process Policy identified that written medication orders would include the dosage expressed in metric system, route, frequency, date, time and signature of the prescriber. Interview with the Director of Pharmacy identified that titration instructions should

include dose rate, interval, monitoring parameter and maximum dose. Physician orders failed to reflect complete orders as per policy.

g. Patient #13 was admitted to the ICU on 5/30/08 with diagnoses that included respiratory failure and pneumonia. Review of the Physician Order dated 5/30/08 at 4:13 PM directed Propofol 10 mg/ml; dose 1000mgs; route: IV to be initiated at 5 mcg per kg per min; titrate q 5 minutes by 5 mcg per kg per min to a maximum 50 mcg/kg/min and titrate to Riker SAS level = -3. Review of the draft for Sedation and Analgesia in ICU Policy and interview with the ICU Nurse Manager identified that the Richmond Agitation Scale (RASS) was utilized for assessment in the ICU, not the Riker scale.

4. * Based on clinical record reviews and interviews with facility personnel for 6 of 8 sampled patients (Patients #1, #2, #3, #4, #9 and #13), the facility failed to ensure that medications were administered in accordance with physician's orders and/or hospital policy. The findings include:

a. Patient #1 was admitted to the hospital on 10/5/07 with shortness of breath. Patient #1 was diagnosed with congestive heart failure and acute MI. Patient #1's code status was changed to "comfort measures only" secondary to poor prognosis. Review of the physician orders dated 10/5/07 identified that the patient was to receive "morphine sulfate IV drip/titrate to comfort"and "Ativan IV 1mg every two hours as needed". Review of the nursing flowsheets and hospital documentation dated 10/5/07 identified that the patient received Morphine Sulfate IV push 2mg, and was started on a Morphine Sulfate IV drip at 2mg/hr at 7:30 PM. Patient #1's Richmond Sedation Agitation Scale was +1(restless). At 7:45 PM, the Morphine IV drip was increased to 6mg/hr with a sedation score of +1(restless). At 7:49 PM, 7:53 PM, and 7:54 PM, Ativan 1mg IV was given (per pyxis). At 8:00 PM, Patient #1's Morphine IV drip was increased to 15mg/hr, with a sedation score of -2 (light sedation). Patient #1 remained on the Morphine IV drip at 15mg/hr with a sedation score of -3 and then a -5 (unarousable) until she expired at 10:15 PM (55mg in 2 hours). Review of the sedation protocol/order sheet failed to identify specific parameters for dosing and/or level of sedation that was required. Interview with MD #4 identified that she had given a verbal order and would have expected the nurse to start the morphine at 2mg an hour and increase by 1-2mg per hour. The hospital did not have sedation protocols and /or policies that addressed monitoring of patients for sedation.

b. Patient #2 was admitted to the hospital on 4/19/08 with sepsis. Review of the physician's orders dated 4/20/08 identified that the patient was to receive Propofol IV initiated at 5mcg/kg/min titrate every 5 minutes to a max of 50. Review of the nursing flowsheets dated 4/20/08-4/21/08 identified that the Propofol had been initiated at 5 mcg with a sedation score of -2 (light sedation). Further review failed to identify that a sedation assessment was completed with subsequent titration.

EXHIBIT A

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Although the ICU plan of care dated 4/20/08 identified that the patient's sedation goal was zero, the nursing flowsheets dated 4/20/08-4/21/08 failed to identify that the patient's sedation medications were titrated to the sedation goal.

c. Patient #3 was admitted to the hospital on 4/15/08 with dehydration and acute renal failure. Review of physician orders dated 4/16/08 identified that the patient was to receive "Propofol IV drip at 10mcg, then titrate for sedation." Further review failed to identify specific parameters/protocols for dosing and/or monitoring. Review of the nursing flowsheets dated 4/16-4/22/08 failed to identify that the patient's sedation medications were titrated to a sedation goal.

d. Patient #4 was admitted to the hospital on 4/15/08 with pneumonia. Review of Physician orders dated 4/19/08 identified that the patient was to receive "Propofol IV drip initiate at 5mcg/kg/min to max of 50mcg-titrate per propofol protocol and Levophed for blood pressure if necessary." Further review failed to identify specific parameters/protocols for dosing and/or monitoring. Review of the nursing flowsheets dated 4/19-4/22/08 identified that the patients Propofol IV drip was started at 20mcg. Further review of nursing flowsheets identified that a sedation assessment was not completed before initiating the Propofol and/or with subsequent titration. Interview with the Nurse Manager on 4/23/08 identified that an assessment of the patient was needed with the initiation of medication and with any changes in titration.

In addition, review of the ICU plan of care dated 4/19/08 identified that although the patient ' s sedation goal was zero, the nursing flowsheets dated 4/19/08-4/22/08 failed to identify that the patient's sedation medications were titrated to the sedation goal determined by the nursing staff. Interview with the Nurse Manager on 4/23/08 identified that although the physician is responsible for ordering the sedation score goal, interview with nursing staff identified that the sedation score is usually determined by the nursing staff. Review identified that the plan of care is individualized for each patient and is initiated at the time of admission and updated every shift.

The hospital did not have sedation protocols and /or policies that addressed monitoring the level of sedation for patients receiving titrated narcotics and/or sedatives.

e. Patient #9 was admitted to the hospital on 5/24/08 with diagnoses that included metastatic ovarian cancer. Review of the clinical record identified that the patient received continuous morphine IV infusion during hospitalization. Review of the Intravenous Narcotic Infusion Policy identified that assessment would include respirations and narcotic effectiveness using 0-10 pain scale and review of the Standard of Care - Pain Management policy identified the need to assess for > 3 discomfort indicators. Review of the Multidisciplinary Flow Sheets dated 5/31/08 through 6/3/08 failed to reflect respirations and pain assessment as per policy and/or

standard of care.

f. Patient #13 was admitted to the ICU on 5/30/08 with diagnoses that included respiratory failure and pneumonia. Review of the physician order dated 5/30/08 at 4:13 PM directed Propofol 10 mg/ml; dose 1000mgs; route: IV to be initiated at 5 mcg per kg per min; titrate q 5 minutes by 5 mcg per kg per min to a maximum 50 mcg/kg/min and titrate to Riker SAS level = -3. Review of the ICU Nursing Flowsheet dated 5/30/08 identified that the Propofol infusion was initiated at the maximum dose of 50 mcg/kg/min and when titration was attempted on 6/3/08, the dose was decreased to 40 mcg/kg/min. Documentation failed to reflect Propofol infusion was administered and titrated as per physician order.

5. * Based on clinical record reviews and interviews with facility personnel for 6 of 8 sampled patients (Patients #1, #2, #3, #4, #5 and #9), the facility failed to ensure that physician orders were accurate and complete and/or reviewed and monitored to ensure patient safety. The findings include:

a. Patient #1 was admitted to the hospital on 10/5/07 with shortness of breath. Patient #1 was diagnosed with congestive heart failure and acute MI. Patient #1's code status was changed to comfort measures only, secondary to poor prognosis. Physician orders dated 10/5/07 identified that the patient was to receive a "Morphine Sulfate IV drip/titrate to comfort "and "Ativan IV 1mg every two hours as needed." Review of the nursing flowsheets and hospital documentation dated 10/5/07 identified that the patient received Morphine Sulfate IV push 2mg, and was started on a Morphine Sulfate IV drip at 2mg/hr at 7:30 PM. Patient #1's Richmond Sedation Agitation Scale was +1(restless). At 7:45 PM, the Morphine IV drip was increased to 6mg/hr with a sedation score of +1(restless). At 7:49 PM, 7:53 PM, and 7:54 PM, Ativan 1mg IV was given (per pyxis). At 8:00 PM, Patient #1's Morphine IV drip was increased to 15mg/hr, with a sedation score of -2 (light sedation). Patient #1 remained on the Morphine IV drip at 15mg/hr with a sedation score of -3 and then a -5 (unarousable) until she expired at 10:15 PM (55mg in 2 hours). Review of the sedation protocol/order sheet failed to identify specific parameters for dosing and/or level of sedation that was required. Interview with Director of Pharmacy on 4/29/08 identified that all pharmacy orders are checked by a pharmacist prior to dosing.

b. Patient #2 was admitted to the hospital on 4/19/08 with sepsis. Review of the physician's orders dated 4/20/08 identified that the patient was to receive "Propofol IV initiate at 5mcg/kg/min titrate by 5mcg/kg/min every 5 minutes to a max of 50." Further review failed to identify specific parameters for sedation.

c. Patient #3 was admitted to the hospital on 4/15/08 with dehydration and acute renal failure. Review of physician orders dated 4/16/08 identified that the patient was to

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receive "Propofol IV drip at 10mcg, then titrate for sedation." Further review failed to identify specific parameters/protocols for dosing and/or monitoring. Interview with the Nurse Manager on 4/23/08 identified that although the physician is responsible for ordering the sedation score goal, the sedation score usually is determined by the nursing staff.

d. Patient #4 was admitted to the hospital on 4/15/08 with pneumonia. Review of Physician's orders dated 4/19/08 identified that the patient was to receive "Propofol IV drip, initiate at 5mcg/kg/min to max of 50mcg-titrate per propofol protocol and Levophed for blood pressure if necessary." Further review failed to identify specific parameters/protocols for dosing and/or monitoring. Review of the nursing flowsheets dated 4/19-4/22/08 identified that the patient's Propofol IV drip was started at 20mcg.

e. Patient #5 was admitted to the hospital on 4/14/08 with pancreatitis. Review of the physician's orders dated 4/22/08 identified that the patient was to receive "Morphine Sulfate IV started at 2mg/hr-titrate to relieve pain/restlessness". Further review failed to identify specific parameters/protocols for dosing and/or monitoring. Interview with the Director of Pharmacy on 4/29/08 identified that all pharmacy orders should have been checked by a pharmacist prior to dosing. Interview with Pharmacist #1 identified that in respect to medication oversight, the nursing staff is asked how patients are doing when pharmacists round on the units. The pharmacy department failed to identify medication policies that directed the review and monitoring of IV drip medications including sedatives, narcotics and hypnotics.

f. Patient #9 was admitted to the hospital on 5/24/08 with diagnoses that included metastatic ovarian cancer. Review of the clinical record identified that the patient received a continuous morphine IV infusion during hospitalization. Review of the physician order dated 5/31/08 at 12:23 PM directed Morphine Sulfate drip 1:1 concentration, 1mg per hour, titrate 1 mg per hour for pain and restlessness, maximum dose 5 mg per hour. A second morphine physician order on 5/31/08 (no time) directed that the morphine drip may be increased every 20 minutes for comfort, to a maximum of 20 mg per hour. Review of the Safe Medication Process Policy identified that written medication orders would include the dosage expressed in metric system, route, frequency, date, time and signature of the prescriber. Questionable orders or problems are resolved prior to dispensing the medication. Interview with the Director of Pharmacy identified that titration instructions should include dose, rate, interval, monitoring parameter and maximum dose. The Director indicated that the Pharmacist should have clarified the morphine orders for completeness regarding the monitoring parameter (i.e. pain). Documentation failed to reflect pharmacy review/oversight of complete narcotic medication orders.

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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (4)(A) and/or (d) Medical records (3) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

6. * Based on review of the clinical record, review of facility policy, review of facility documentation, and interview, the facility failed to ensure that all safety precautions to prevent injury were implemented for one patient, Patient #24, during Magnetic Resonance Imaging (MRI) study. The findings include:

    a. Patient #24 had physician orders dated 1/15/08 for a Magnetic Resonance Imaging (MRI) study, for diagnosis of a rotator cuff tear. Interview with Radiology Technologist #1 (RT #1) on 7/31/08 at 10:20 AM identified that she was the scanning technologist and was responsible for screening Patient #24 for the 1/15/08 MRI. RT #1 stated that she was aware that patients should not have direct contact with the inside (bore) of the MRI machine and that although patients are usually padded to prevent direct skin to bore contact, Patient #24 was wearing a thick flannel shirt and therefore believed that the flannel shirt would provide enough padding for the patient. Interview with RT #2 on 7/31/08 at 11:42 AM identified that he assisted RT #1 in positioning Patient #24 on the MRI table. RT #2 stated that Patient #24 was wearing a regular dress shirt, not a flannel shirt. RT #2 stated that Patient #24's body habitus was fairly broad and that the patient complained of pressure on his sides from the machine as soon as the table began moving into the machine. RT #2 stated he instructed Patient #24 to utilize the emergency call button if he was unable to tolerate it. Review of the of the MRI Patient Screening Form Part B dated 1/15/08 identified that during the procedure, Patient #24 reported that he felt "warm" on the left arm. The documentation by RT #1 identified that she asked Patient #24 if he could tolerate the warm feeling for one more scan and that the patient responded that he could. The documentation identified that after the patient was allowed to reposition his left arm, the scan was completed. RT #1 stated that she did not stop the scan to check the patient because the patient only described the feeling as "warm" not hot. Interview with Patient #24 on 8/21/08 identified that he wore a dress shirt, not a flannel shirt, on the day of the MRI. Patient #24 stated that he was asked by the RT to reposition himself in order to get a better view of the shoulder and that when he did, his arm made contact with the inside of the machine. Patient #24 stated that it was at this point that he began to have the warm feeling in the left arm. Following the MRI procedure, Patient #24 was sent directly to the Radiology Department for additional x-rays where a 4.0 by 5.0 centimeter (cm.) area with blistering was observed on the patient's left forearm. Patient #24 was subsequently sent to the Emergency Department for further evaluation and treatment. Interview with the Radiologist, MD #30, on 7/31/08 identified that Patient #24's body habitus may have been a contributing factor in the event. MD #30 stated that if cloth or a sheet were to be used to protect the skin during an MRI, the sheet might have to be folded over several times to provide enough padding. Interview with plastic surgeon,

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MD #5, on 9/3/08 identified that when he saw Patient #24's burn on 1/16/08, he thought that it was a superficial contact burn. MD #5 stated that when he saw the area again on 1/26/08, the burn was actually a Radio Frequency (RF) burn that was much deeper and required multiple debridement procedures that included removal of tissue down to the fascia on top of the muscle. Interviews with RT #1 and RT #2 identified that prior to this event, facility practice did not routinely direct padding to be used during an MRI unless there was a potential for direct skin to bore contact. Subsequent to this event, the facility developed a policy that directed that that if patient's body habitus results or is likely to result in any of the patient's tissue touching the bore, coil, leads, or wires, then manufacturer's recommended foam pads shall be placed between the patient's tissue and the aforementioned parts. The policy further directed that the examination would be terminated if a patient complained of excessive bodily heating during the exam even if the patient indicated that he/she was fine to proceed with the examination. Interview with the Clinical Director of MRI services on 7/30/08 identified that in addition, the facility's MRI service adopted a practice whereby all patients must have side padding placed before the start of an MRI and that if the padding can not be placed due to body habitus, the patient will not be able to receive the MRI at that facility. Review of documentation from a second plastic surgeon who examined the patient, MD #6, identified that Patient #24 had sustained a full thickness burn that was healed but may require additional surgical intervention related to an unstable scar at the patient's left forearm.

The following are violations of the Connecticut General Statutes Section 46a-152(d) and/or the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (d) Medical records (3) and/or (e) Nursing services (1) and/or (i) General (6).

7. Based on review of the clinical records, review of facility policies, and interviews, the facility failed to ensure that a physician order and/or that a face to face evaluation after the initiation of a restraint was obtained in accordance with facility policies for one (1) of three (3) patients reviewed, Patient #94, who required the use of restraints in the Emergency Department. The findings include:

    a. Patient #94 arrived in the ED at 7:17 PM on 6/2/08 after sustaining an injury during an assault and was identified as intoxicated. Upon arrival, Patient #94 expressed thoughts of suicidal ideation. Review of the ED admission record identified that at 7:40 PM, Patient #94 became uncooperative, attempted to bite staff, and required four point restraints. Review of the restraint observation record identified that Patient #94 remained in four point restraints until 4:15 AM (6/3/08), in two point restraints until 6:00 AM and in a one point restraint until 7:45 AM on 6/3/08, when the last restraint was removed. Review of the clinical record with facility staff lacked documentation of physician orders for the restraints, a face to face evaluation by a Licensed Independent Practitioner (LIP) for restraints to continue, or renewal of the

restraint orders when the patient remained in restraints for more than four hours. Review of the facility's restraint policy directed that an order from an LIP must be obtained within the first hour of a patient being place in restraints and that the LIP must conduct a face to face evaluation in that same time frame. In addition, the policy directed that if the patient continued to require restraint after four hours, a telephone order must be obtained from the LIP to continue the restraint with documented rationale of the reason for continuation of the restraint. Interview with the Quality Coordinator on 7/31/08 identified that she believed that Patient #94's order sheets had been misplaced/misfiled but was unable to provide the documentation.

8. Based on review of the clinical record, observations, and interviews, the facility failed to ensure that physician orders for Venodyne boots were consistently implemented for two (2) patients reviewed, Patients #124 and #134 and/or that medication was administered in accordance with physician orders for one patient, Patient #14. The findings include:

   a. Patient #124 was admitted to the facility on 7/27/08 with diagnoses that included Gastrointestinal (GI) bleeding and anemia. Physician orders dated 7/27/08 directed the continuous application of Venodyne boots (compression boots to prevent blood clot formation). Observation on 7/28/08 at 9:55 AM identified that a Venodyne compression pump was at the foot of Patient #124's bed, but the patient's bilateral leg wraps were not in place. Interview with facility staff identified that the patient had just returned from the bathroom and that staff had not yet had an opportunity to reapply the leg wraps. A second observation with the Quality Coordinator on 7/29/08 at 12:15 PM identified that although Patient #124 had the leg wraps in place, the compression pump was not operational. Interview with RN #20 at the time of the observation identified that she had forgotten to turn on the compression pump when she applied Patient #124's leg wraps earlier in the morning. Subsequent to surveyor inquiry, the pump was turned on and working.

   b. Patient #134 was admitted to the facility on 7/21/08 with diagnoses that included Gastrointestinal (GI) bleeding. Physician orders dated 7/23/08 directed the application of Venodyne boots. Observation of Patient #134 on 7/29/08 at 10:15 AM identified that the patient was sitting up in a bedside recliner chair with bilateral Venodyne leg wraps in place. Interview with the patient at the time of the observation identified that she did not believe the compression boots were working as she had previously used them and that they "didn't feel right". Upon further observation, the Venodyne compression pump was found to be unplugged. Subsequent to surveyor inquiry, the pump was plugged into the electrical outlet and was operational. Interview with RN #30 at the time of the interview identified that he was unable to explain why the pump had been unplugged.

   c. Patient #14 was admitted to the hospital on 2/4/08 with a past medical history that

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included myocardial infarction, coronary heart disease, hypertension, and atrial fibrillation. Review of the clinical record identified that on 2/4/08 the patient underwent a right hip arthroplasty. Review of the clinical record dated 2/7/08 identified that Patient #14 developed chest pain; rapid atrial fibrillation (A-fib) with heart rates that ranged from 130 to 140 beats per minute (bpm) and was subsequently transferred to the intensive care unit for close monitoring. Review of the Critical Care records dated 2/9/08 at 10:00 PM through 2/10/08 at 5:00 AM identified that the patient was in A-fib and had episodes of premature ventricular contractions with heart rates that ranged from 103 to 119 bpm. In an interview on 9/5/08, RN #10 identified that she notified MD #10 of the patient's elevated heart rate and was subsequently given an order to administer Digoxin 0.25 milligrams (mg) intravenously now and then 0.25 mg every six (6) hours for a total of four (4) doses. Review of the Pyxis dispensing record dated 2/10/08 at 5:46 AM identified that RN #10 had removed 5 vials (each vial contained 0.5 mg) of Digoxin. Review of the medication administration record dated 2/10/08 identified that RN #10 administered 2500 micrograms (2.5 mg) of Digoxin at 5:46 AM. RN #10 identified that following administration of the medication, she called the pharmacy to inform them that she had overrode the pyxis system to administer the Digoxin to the patient. RN #10 was informed by the pharmacist that the dosage of Digoxin administered was incorrect and at that point (approximately 6:00 am) RN #10 realized she administered 2.5 mg of Digoxin instead of the ordered 0.25 mg. RN #10 stated that when she received the telephone order for the Digoxin at 5:40 AM, during the read back process MD #10 had to correct her and restate the Digoxin order and although he repeated the order, RN #10 administered the incorrect dose. RN #10 stated that she immediately notified MD #10, the charge nurse and the nursing supervisor of the medication error. RN #10 stated that an external pacemaker was applied to the patient per MD #10's instruction and stated that although the patient was continuously monitored, the clinical record lacked documentation of all these assessments. Review of the Medication Administration policy identified that the nurse would read the label of the medication two times (check medication upon removing from Pyxis drawer against physician's order) and verify the proper time, dose and route of the medication to be administered. Interview with RN #10 identified that she had not followed this process. During an interview on 7/30/08, MD #10 identified that the patient received 10 times the amount of Digoxin ordered and that the patient subsequently received an antidote to decrease the toxicity of the overdose. MD #10 identified that subsequent to the medication error, the patient was hemodynamically stable with a heart rate that ranged from 60 beats per minute to the 70's.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical record (3) and/or (e) Nursing services (1) and/or (i) General (6).

9. Based on review of Emergency Department admission records, review of facility policies, and interview, the facility failed to provide documentation of an assigned triage level upon

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completion of the initial nursing assessment for three (3) of six (6) patients received who required services in the Emergency Department, Patients #144, #174, and #404. The findings include:

a. Patient #144 arrived at the Emergency Department (ED) on 7/29/09 with complaints of epigastric and chest pain and was triaged at 1:55 PM. Review of Patient #144's ED admission record lacked documentation of an assigned triage level.

b. Patient #174 arrived at the ED on 7/28/08 with complaints of a cough and was triaged at 8:55 PM. Review of Patient #174's ED admission record lacked documentation of an assigned triage level.

c. Patient #404 arrived at the ED on 7/28/08 with complaints of nausea and headache following a fall at home and was triaged at 8:20 PM. Review of Patient #404's ED admission record lacked documentation of an assigned triage level.
Review of facility policy directed that a triage level be assigned upon completion of the triage process and that the category assigned would be documented in the patient's ED record. Interview with the Nursing Director of the ED on 7/31/08 identified that the department had recently adopted a five level triage system and that the ED staff was still adjusting to the new policy.

10. * Based on review of the clinical record, review of facility policy, observations, and interviews, the facility failed to ensure that preventive measures were consistently implemented in accordance with the plan of care for two (2) of three (3) patients reviewed, Patients #114 and #134, who were identified by the facility to be at risk for pressure ulcers. The findings include:

a. Patient #114 was admitted to the facility on 7/24/08 with diagnoses that included Gastrointestinal (GI) bleeding. Review of the nursing admission assessment dated 7/21/08 identified that Patient #114 entered the facility without a pressure sore though had a reddened area on the right buttocks. A Braden Scale assessment upon admission identified that Patient #114's score was thirteen (13) and therefore was at risk to develop pressure sores during the hospitalization. Facility policy directed that patients whose Braden Score was identified to be between twelve (12) and sixteen (16) would have appropriate preventive interventions put in place. Review of the care plan dated 7/24/08 identified Patient #114's risk for skin impairment with interventions that included keeping the patient's heels off loaded to prevent pressure on the heels. The documentation identified that on 7/26/08, Patient #114 developed a 3.5 centimeter (cm.) by 2.5 cm. suspected Deep Tissue Injury (DTI) on the left heel. Revisions to the plan of care included the addition of a waffle boot. Observation on 7/29/08 at 11:45 AM identified that although the waffle boot was present on Patient #114's left heel, the patient's right heel was resting on the bed without the benefit of off loading pressure to the site.

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b. Patient #134 was admitted to the facility on 7/21/08 with diagnoses that included Gastrointestinal (GI) bleeding. Review of the nursing admission assessment dated 7/21/08 identified that Patient #134 entered the facility without a pressure sore or other skin impairment. A Braden Scale assessment upon admission identified that Patient #134's score was fourteen (14) and therefore was at risk to develop pressure sores during the hospitalization. Subsequent Braden assessments through 7/28/08 continued to identify that Patient #134 was at risk for skin issues. Review of the care plan dated 7/22/08 identified Patient #134's risk to develop skin integrity issues with interventions that included the use of an overlay air mattress. Observation on 7/29/08 at 10:15 AM identified no air mattress present on the patient's bed. Interview with the Quality Coordinator at the time of the observation identified that she thought that Patient #134 had refused the air mattress placement. A subsequent interview with Patient Care Assistant #1 at 10:30 AM identified that he thought he had heard in report that the patient refused to have the air mattress placed. Interview with Patient #134 at 10:35 AM identified that Patient #134 denied refusing and/or having been offered the air mattress and accepted placement of the mattress overlay.

In addition, observation on 7/29/08 at 10:15 AM identified that Patient #134 was sitting in a bedside recliner chair. Interview with Patient #134 at the time of the observation identified that the patient stated that she had been out of bed since just after breakfast and complained of tenderness on her bottom. Observation of the patient's seating arrangement with the assistance of facility staff identified that there was no pressure reducing/pressure relieving chair cushion on the recliner chair. At 12:05 PM, Patient #134 requested to go back to bed. Patient #134 complained of being uncomfortable after sitting up so long and that she was unable to move around and change her position while in the recliner chair. Upon the patient's transfer back to bed, no chair cushion was observed on the recliner chair seat despite complaints of tenderness by the patient nearly two hours earlier. Observation of the patient's skin upon return to bed identified that Patient #134 had developed an approximately 6.0 centimeter (cm.) by 4.0 cm. blanchable, reddened area on the coccyx/buttocks area. Review of facility policy directed that patients scoring a total Braden Score assessment of less than eighteen (18) be provided with preventive interventions including a chair cushion.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (4)(A) and/or (d) Medical records (3) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

11. * Based on review of the clinical record, review of facility policy, and interview, the facility failed to ensure that a pre and post procedure assessment were completed by a Radiology Technologist for one patient, Patient #24, who required outpatient services. The findings include:

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a. Patient #24 had physician orders dated 1/15/08 for an outpatient diagnostic procedure, a Magnetic Resonance Imaging (MRI) study, for diagnosis of a rotator cuff tear following a fall. Although review of the MRI Patient checklist identified that Patient #24's magnetic safety check was completed, review of the MRI Patient Screening Form Part B dated 1/15/08 lacked documentation to reflect that a complete assessment was provided including questions related to allergies and/or medications prior to the procedure. Interview with Radiology Technologist #1 (RT #1) on 7/31/08 at 10:20 AM identified that toward the end of the procedure, Patient #24 reported that he felt "warm" on the left arm, that she asked the patient if he could tolerate one more scan, and that the patient reported that he could if he could just reposition his left arm. RT #1 stated that she then completed the scan. The documentation failed to reflect that a post procedure assessment was completed by RT #1. RT #1 stated that she did not assess Patient #24's left arm upon completion of the scan because the patient did not complain again once the scan was completed. Review of facility policy directed that pre screenings be completed that included screening for allergies and medications taken prior to the procedure. In addition, the policy directed that a post procedure assessment including an assessment for pain, discomfort, and or impairment be completed. Following the MRI procedure, Patient #24 was sent directly to the Radiology Department for x-rays where a 4.0 by 5.0 centimeter (cm.) area with blistering was observed on the left arm by MD #30. Patient #24 was subsequently sent to the Emergency Department for further evaluation and treatment that included a Tetanus injection and Bacitracin gauze dressing with discharge instructions to follow up with his primary physician. Patient #24 was subsequently identified to have a Radio Frequency burn that required multiple debridement procedures.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (3) and/or (e) Nursing services (1) and/or (i) General (6).

12. Based on a review of the clinical record, review of facility policy, and interviews, the facility failed to ensure that the clinical record was accurate and/or complete for one patient, Patient #14. The findings include:

a. Patient #14 presented to the Emergency Room on 2/4/08 with a chief complaint of hip pain. Review of the clinical record with MD #300 on 9/12/08 identified that although the patient had an electrocardiogram (EKG) performed while in the ED on 2/4/08 at 2:00 pm, the EKG report could not be located for review. MD #300 stated that the missing document was considered the baseline EKG that she referred to in the patient's History and Physical.
Review of Patient #14's physician's order dated 2/10/08 at 6:45 AM, directed a STAT (now) electrocardiogram (EKG) be performed. Review of the EKG report dated 2/10/08 identified that the test was not performed until 6:30 pm (twelve-hours

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later). Interview with the Nurse Manager on 7/31/08 identified that the time on the EKG report was incorrect and should have reflected that the EKG was performed at 6:30 AM.

Review of facility documentation dated 2/10/08 identified that RN #10 erroneously administered 2.5 mg of Digoxin to Patient #14 instead of the ordered 0.25 mg at 5:46 AM. During an interview on 9/5/08, RN #10 identified that she realized she had made a medication error at approximately 6:00 am and immediately notified MD #10 (not documented) who directed that an external pacemaker be applied to the patient for continuous monitoring. Review of the clinical record with Nurse Manager (on 7/31/08) identified that the patient's heart rate was documented at 6:00 AM (98 beats per minute) and 7:00 AM (71 bpm). Although RN #10 stated that the patient was continuously monitored and that an external pacer was applied to the patient, the clinical record lacked documentation to reflect any additional assessments and/or monitoring of the patient's status during the period of 6:00 AM through 8:00 AM. Review of the Documentation policy directed that ongoing nursing assessments would be documented every four-hours or more frequently if the patient's condition dictates. Interview with the Nurse Manager stated that the continuous monitoring strips are not maintained once the patient is discharged from the hospital.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(B) and/or (d) Medical records (3).

13. Based on review of the clinical records, review of facility policies, and interviews, the facility failed to ensure that all entries into the clinical record were dated and timed in accordance with facility policies for one (1) of three (3) patients reviewed, Patient #84, who required the use of restraints in the Emergency Department. The findings include:

    a. Patient #84 was brought into the Emergency Department (ED) on 7/21/08 at 10:38 PM by the local police department with symptoms of irrational behavior. Review of the ED admission record identified that Patient #84 became assaulting toward staff while in the ED and required four point restraints at 12:30 AM (7/22/08). Review of the Behavioral Restraint Order Sheet lacked documentation to reflect the date and time that the Licensed Independent Practitioner (LIP) completed the face to face evaluation of Patient #84's need for restraints in accordance with facility policies. Review of the facility's restraint policy directed that an order from an LIP must be obtained within the first hour of a patient being place in restraints and that the LIP must conduct a face to face evaluation within the same time frame. Facility policy further directed that all entries into the clinical record be dated and timed.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (4)(A) and/or (g) Pharmacy (1) and/or (i) General (6).

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14. Based on observations and interviews with facility personnel, the facility failed to ensure that only authorized personnel have access to locked medication areas. The findings include:

    a. During tour of the operating room on 7/30/08, it was observed that a general service assistant had access and opened the anesthesia work room which included medications and biologicals. Interview with the Director of Anesthesia on 7/30/08 identified that only licensed practitioners and anesthesia assistants should have access to this room. Subsequent to surveyor inquiry, the code for the anesthesia work room was changed immediately.

15. Based on observations and interviews with facility personnel, the facility failed to ensure that outdated medications were not utilized for patient usage. The findings include:

    a. During tour of the ambulatory care unit on 7/30/08, it was observed that a vial of Bupivacaine 0.5% dated 8/1/07 and 2 blood culture bottles dated 2/29/08 and 6/30/08 were outdated and located in the medication room. Subsequent to surveyor inquiry, the vials and bottles were removed. Interview with the Nurse Manager on 7/30/08 identified that these were anesthesia medications and she was unaware that they were in the cabinet.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (4)(A) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

16. * Based on review of facility policies, review of facility documentation, and interview, the facility failed to ensure that routine maintenance checks of the facility's Magnetic Resonance Imaging (MRI) machine were performed timely. The findings include:

    a. Interview with the Clinical Manager of MRI Imaging on 7/30/08 identified that the facility policy directed that the MRI machine have a preventative maintenance evaluation scheduled every two months. The Clinical Manager stated that a representative from the company from whom the MRI was purchased, performs the maintenance. Review of facility documentation identified that a preventive maintenance inspection was performed on 10/21/07. The documentation provided by the facility was unclear as to whether or not the MRI machine required any adjustments and/or replacement parts at the time of the 10/21/07 preventive maintenance visit. Although a preventive maintenance inspection on the MRI machine was due by 12/21/07, the; facility was unable to provide documentation of an inspection during the month of December, 2007. On 1/15/08, one patient, Patient #24, sustained a burn on the left forearm during an MRI procedure at the facility. Interview with facility staff on 9/3/08 identified that the MRI company was called on 1/15/08 and that an offsite inspection was completed with no findings related to the operation of the machine. The facility was unable to provide documentation of the off site inspection and multiple attempts to contact multiple representatives from the

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company who provided the maintenance services were unsuccessful. On 1/23/08, an onsite inspection of the MRI was completed. The documentation provided by the facility was unclear as to whether or not the MRI machine required any adjustments and/or replacement parts at the time of the 1/23/08 inspection. Interview with Radiologist, MD #20, on 9/3/08 identified that he did not believe that Patient #24's burn was a result of mechanical failure but a result of the patient's arm touching the inside of the MRI machine.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

17. Based on observations and interviews with facility personnel, the facility failed to ensure that trash was stored in proper receptacles. The findings include:

    a. During tour of the operating room on 7/30/08 it was observed that multiple garbage bags and empty boxes were sitting on the floor in the biohazardous waste room. Subsequent to surveyor inquiry, the trash bags and boxes were removed and a plastic receptacle was placed in the biohazardous room for trash. Interview with the Nurse Manager on 7/30/08 identified that the garbage bags and boxes should not have been on the floor and maintenance would immediately remove them.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(B) and/or (d) Medical records (3) and/or (i) General (6).

18. Based on clinical record review and interviews with facility personnel for one (1) of one (1) patients reviewed, Patient #34, the facility failed to ensure that a post anesthesia evaluation was completed prior to discharge. The findings include:

    a. Patient #34 was admitted on 9/6/07 for a Hysteroscopy, Dilation and Curettage and a Diagnostic Laparoscopy. Review of the anesthesia record identified that the patient had received Fentanyl 250mcg intraoperatively. Further review identified that post operatively the patient received an additional 200mcg for identified pain levels of 7 and 8 out of 10 (10 is severe pain). Review of hospital policy identified that a patient may be discharged from the facility by a licensed independent practitioner decision or by medical staff approved criteria, however, Patient #34 had an extended stay postoperatively due to nausea and pain control issues. Review of the post anesthesia order sheet and/or progress notes failed to identify that, despite Patient #34's problems with nausea and pain, a post operative anesthesia assessment was completed prior to discharge. Interview with the Nurse Manager on 8/1/08 identified that hospital practice includes completion of a post anesthesia assessment by the anesthesia provider prior to discharge.

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The following are violations of the Connecticut Administrative Regulations Section 19-24d-3 through 19-24d-11.

19. On August 8, 2008 during an inspection of the facility, the following was reviewed: records, procedures, equipment and facilities, which included in-house physics reports and follow up corrective actions, personnel dosimetry records, records of receipt of radioactive materials, quarterly inventories, records of area surveys, records of calibration of available radiation detection instrumentation, calibration of the dose calibrator including linearity and constancy determinations and leak test records.

    a. Section 19-24d-3(a) requires, in part, that no person shall make, sell, lease, transfer, lend or install x-ray or fluoroscopic equipment unless such supplies and equipment when properly placed in operation and properly used, will meet the requirements of Sections 19-25-d-3 to 19-25d-11, inclusive.

    b. Section 19-24d-3(b) (1) requires, in part, that the owner shall be responsible for assuring that all requirements of Sections 19-25d-3 to 19-25d-11, inclusive, are met.

    c. Section 19-24d-3(b)(2) requires that the owner shall assure that all x-ray equipment under his control is operated only by individuals adequately instructed in safe operating procedures and competent in safe use of the equipment.

Contrary to the above, Bristol Hospital installed fluoroscopic equipment and did not assure that all requirements of Sections 19-24d-3 to 19-24d-11 were met. Specifically, individuals were allowed to use fluoroscopic equipment who the owner did not assure were adequately instructed in safe operating procedures and competent in safe use of the equipment.